

Message Text

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PAGE 01 STATE 204688
ORIGIN HEW-06

INFO OCT-01 ARA-14 EA-12 NEA-10 ISO-00 OES-07 EB-08
COME-00 /058 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:CM
APPROVED BY OES/APT/BMP:MCRAWFORD
DHEW/OIH:MKEFAUVER
EA/JCHRISTENSON(INFO)
ARA/AND/V:TWSONANDRES(INFO)
EA/ROC:DGBROWN(INFO)
NEA/ARN:TJCAROLAN(INFO)
ARA/MEX:GFALK(INFO)

-----083010 270536Z /15

P 262035Z YUG 77
FM SECSTATE WASHDC
TO AMEMBASSY CARACAS PRIORITY
AMEMBASSY TOKYO PRIORITY
AMEMBASSY TAIPEI PRIORITY
AMEMBASSY DAMASCUS PRIORITY
AMEMBASSY MEXICO PRIORITY

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E.O. 11652: N/A

TAGS: OGEN, ETRD, EIND, TBIO, VE, JA, SY, TW, MX

SUBJECT: FDA ADVISORY - POSSIBLE ELECTRICAL SHORT IN
POWER CORD (RECALL T-139-7)

FDA ADVISES OF THE FOLLOWING:

1. PRODUCT INVOLVED: SARNS DUAL COOLER-HEATER,MODEL 1160.
PRODUCT IS A MEDICAL DEVICE, USED IN CARDIOVASCULAR AND
OTHER THORACIC SURGERY. IT IS A PORTABLE SOURCE OF HOT AND
COLD WATER,
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WHICHIS DELIVERED TO A HEAT EXCHANGER
(SEPARATE UNIT FROM THE COOLER/HEATER UNIT). PATIENT
COOLING OR TEMPERATURE REGULATING IS BY CIRCULATING THE
PATIENTS BLOOD THRU THE HEAT EXCHANGER.

THE HEATER/COOLER UNIT ID CONJUNCTION WITH THE HEAT EX-

CHANGER UNIT IS TO BE USED UNDER THE SUPERVISION OF A PHYSICIAN, AND IS SOLD PRIMARILY TO HOSPITALS, MEDICAL CENTERS AND CLINICS.

PRODUCT IDENTIFICATION: THE HEATER/COOLER UNIT IS LABELED AS FOLLOWS ON THE BOTTOM OF THE REAR PANEL, "CARDIOVASCULAR EQUIPMENT, SARNS INC., ANN ARBOR, MIC;IGAN CODE 11160 SERIAL NO. XXX VOLTAGE 115 CYCLE 60 DANGER DO NOT USE IN AN EXPLOSIVE ATMOSPHERE. WARNING USE SEPARATE 20 AMP

AC GROUNDED OUTLET 115 V 60 HZ 15 AMP. ON THE FRONT TOP PANEL OF THE UNIT, THERE ARE INSTRUCTIONS FOR UNIT SET UP, PRIMING, HYPOTHERMIA, RE'ARMING NORMOTHERMIA, OVER-HEATING SAFETY PROCEDURE AND CONTAINS THE FOLLOWING WARNING. "WARNING: THE SARNS DUAL COOLER-HEATER IS NOT AN AUTOMATIC TEMPERATURE REG'LATING SYSTEM.RESPONSIBILITY FOR MONITORING AND MAINTAINING PATIENT TEMPERATURE REMAINS WITH THE OPERATOR AND HIS STAFF".

MANUFACTURING/RECALLING FIRM: SARNS INC
6200 JACKSON ROAD
ANN ARBOR, MICHIGAN
CF 20756

2. REASON FOR RECALL: EXAMINATION OF THE POWER CORD BEHIND THE REAR ACCESS PANEL REVEALED THAT THE INSULATION HAD MELTED OFF ONE OF THE WIRES, AT A POINT JUST BEFORE UNCLASSIFIED

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THE CONNECTOR USED TO CONNECT THE POWER CORD TO THE INTERNAL UNIT WIRING, THUS EXPOSING BARE WIRING FOR ONE QUARTER INCH. SERVICE REPORT INDICATES THAT ORIGINAL POWER CABLE (BLUE) WITH 16 GUAGE WIRING WAS REPLACED WITH BLACK POWER CABLE WHICH HAS 14 GUAGE WIRING. FIRM STATES BLACK POWER CABLE HAS HEAVIER GUAGE WIRING WHICH IS SAME AS THAT OF INTERNAL WIRING OF UNIT. ALL MELTED INSULATION HAS OCCURED ON POWER CABLE SIDE OF INTERNAL CONNECTIONS. FIRM COMMENCED RETROFIT OF POWER CABLES ON JULY 5, 1977 AND ALL UNITS PRODUCED SINCE APRIL 19, 1977.

3. POSTS ARE REQUESTED TO CONTACT CONSIGNEES TO DETERMINE IF THEY HAVE RECEIVED MODIFICATION KITS WITH REPLACEMENT INSTRUCTIONS DATED JULY 25, 1977. ANY QUESTIONS CONSIGNEES MAY HAVE REGARDING RECALL SHOULD BE DIRECTED TO FIRM.

4. FOREIGN CONSIGNEES AS FOLLOWS:

EQUISA (C/O MR. R. MARTIN)
APARTADO 50.687
SA3 GRANDE

CARACUS, VENEZUELA

JAPAN MEDICAL SUPPLY CO. LTD.

C/O MR. IVAO YAMASAKI

1

2-17 KAKO-MACHI

HIROSHIMA 7733, JAPAN

SAWAH & CO.

B. P. 2308

PLACE AZME

DAMASCUS, SYRIA

KOFA COMPANY LTD.

C/O MR. HOMER PH. H. LIN

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POST OFFICE BOX NO. 3001

TAIPEI, TAIWAN

REPRESENTACIONES

C/O MR. MANUAL GARRIDO

MEDICOTECNICAS S.A.

MAZATLAN NO. 83

MEXICO 11, P.F. CHRISTOPHER

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NNN

*** Current Handling Restrictions *** n/a

*** Current Classification *** UNCLASSIFIED

Message Attributes

Automatic Decaptioning: X
Capture Date: 01-Jan-1994 12:00:00 am
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: ELECTRIC EQUIPMENT, RECALLS
Control Number: n/a
Copy: SINGLE
Sent Date: 26-Aug-1977 12:00:00 am
Decaption Date: 01-Jan-1960 12:00:00 am
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01-Jan-1960 12:00:00 am
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1977STATE204688
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, M.D.:CM
Enclosure: n/a
Executive Order: n/a
Errors: n/a
Expiration:
Film Number: D770310-0509
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1977/newtext/t197708114/aaaafzpk.tel
Line Count: 149
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON MICROFILM, TEXT ON-LINE
Message ID: 6282b350-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 3
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 09-Dec-2004 12:00:00 am
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 1443525
Secure: OPEN
Status: <DBA CORRECTED> gwr 970912
Subject: FDA ADVISORY - POSSIBLE ELECTRICAL SHORT IN POWER CORD (RECALL T-139-7) FDA ADVISES OF THE FOLLOWING
TAGS: EIND, ETRD, OGEN, TBIO, JA, MX, SY, TW, VE, OGEN
To: CARACAS MULTIPLE MULTIPLE
Type: TE
vdkgvwkey: odb://SAS/SAS.dbo.SAS_Docs/6282b350-c288-dd11-92da-001cc4696bcc
Review Markings:
Margaret P. Grafeld
Declassified/Released
US Department of State
EO Systematic Review
22 May 2009
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